

# PSI's MedDRA Support Services

## eCert Solution

### "Consult the Experts"

#### eCert Solution – a Corporate Investment Preserver

The decision makers within the biopharmaceutical industry are continuously challenged to invest additional dollars towards implementing and maintaining their MedDRA solutions. However, quite frequently, the question on their mind before investing any additional money is: What is my organization's return on investment (ROI) already made? While it is prudent of management to ask this question, unfortunately, quite frequently the basis of this question lies in their frustration that comes from observing the MedDRA-related problems within their organizations. It is difficult for them to comprehend why, after expending hundreds of thousands of dollars in training and consultation, the coders continue to perform inconsistent coding; why the Quality Assurance (QA) procedures are not resulting in increased quality; and why they cannot state, with assurance, the resources they have really understand and follow the organizational coding principles, guidelines, and standard operating procedures (SOPs).

PSI recognized this problem some time ago and developed a methodology, centered on an in-house, automated tool that fulfills three objectives:

- **Train the Coders** in a manner that ensures that they not only learn the MedDRA concepts, but also the organization's coding principles and guidelines.
- **Certify Proficiency in Coding** by testing their knowledge of MedDRA as well as

the organizations coding principles, guidelines, and SOPs.

- **Perform Quality Assurance** to ensure consistency among the customer's internal coding team or other coding entities (i.e., Contract Research Organizations (CROs)), and promote continuous improvement.

#### Training through PSI's eCert Solution

PSI has taken MedDRA training to new heights by developing and offering the eCert Solution. One of the most common problems in the industry is that the coders within organizations do not follow a consistent set of coding principles, even after they have been trained in MedDRA. Quite often, the lack of coding consistency among their in-house and third-party coders stems from the fact that the coders have attended general MedDRA coding training sessions but possess limited or no knowledge of the corporate's coding culture, philosophy, and principles. Consequently, discrepancies in coding among coders are quite common.

PSI's eCert training concept is based on 'mentor/protégé' relationship where the coders are trained, using the clients own data/narratives or terms, coding guidelines, and standard operating procedures (SOPs), as well as a PSI-provided automated tool, to certify the individual's proficiency in MedDRA coding concepts.

The mentor is an experienced PSI-certified coder or QA Specialist while the protégé is the coder being introduced into a corporate coding environment. The length of time an

individual needs mentoring depends on the individual's education, prior experience in MedDRA coding, and the level of proficiency required. The mentor provides virtual, real time feedback that continuously improves the protégé's coding skills and knowledge while the eCert Solution maintains an audit trail to measure the protégé's progress through the course of training.

PSI offers mentors on-site or remotely using the eCert Solution no matter where the trainees are located. If you would rather use internal mentors, but are interested in using PSI's automated tool, we will work with you to accommodate that specific need. Our customers consider the eCert Solution the most promising and cost effective mechanism for measuring and preserving their investment in MedDRA coding proficiency and organization-wide coding uniformity.

### Certification through eCert Solution

Once the coders have been trained, it is important to ascertain that they understood, retained, and are using the concepts of MedDRA as well as the knowledge of organization's coding principles, guidelines, and SOPs. The eCert Solution can be used to accomplish this objective. It can be used to periodically test your coding team's consistency by using selected narratives or terms and asking the members to code using your organization's SOPs and guidelines.

The assigned PSI-certified Coders or QA Personnel will conduct such tests and provide immediate feedback on the coding results. The process allows an organization to determine the proficiency level of each coder and help determine who needs further assistance in working more consistently with the team according to prescribed standards or who may simply not 'cut the mustard.'

### QA through eCert Solution

Many organizations have realized the need for an independent third party to perform QA of the coding done by their CROs or internal staff. eCert Solution was specifically developed to accommodate this need. It was created to allow free access to coding results by certified QA Personnel for the purpose of determining the degree of accuracy of each coder's work. It allows the QA Person to correct the codes and note the nature of the error such that the coding can continue to move through the coding process and the coders responsible for the inaccuracies will have the benefit of the adjustments made. This process offers input for continuous improvement of coding both as individuals and as a team.

### PSI : Uniquely Qualified

PSI is uniquely qualified to help your organization in implementing MedDRA solutions. We have processed over 1.3 million individual safety reports for the FDA and coded over 13 million terms in MedDRA. No other organization can claim this experience. Our global perspective includes those of the reporting organizations and the receiving authority. We have served such organizations in both the pre- and post-marketing environments.

Our eCert Solution preserves your investment in MedDRA. It supports your MedDRA Team as you test, assess, document, and continuously improve the quality of your MedDRA Coding.

For more information about our services and PSI Electronic Training Series (PETS) products, visit our web site, [www.MedDRAHelp.com](http://www.MedDRAHelp.com). For references regarding MedDRA projects that PSI has successfully completed, please contact Bill York at 703.352.9482 or via email at [byork@psiint.com](mailto:byork@psiint.com).

### Consult the Experts!